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| <b>(21) International Application Number:</b> PCT/US99/21416<br><b>(22) International Filing Date:</b> 17 September 1999 (17.09.99)<br><br><b>(30) Priority Data:</b><br>09/159,467 23 September 1998 (23.09.98) US<br><br><b>(71) Applicant:</b> SENORX, INC. [US/US]; Suite 144, 13677 Alton Parkway, Irvine, CA 92618 (US).<br><br><b>(72) Inventors:</b> BURBANK, Fred, H.; 30982 Steeplechase Drive, San Juan Capistrano, CA 92675 (US). LUBOCK, Paul; 30 Bethany, Laguna Niguel, CA 92677 (US). JONES, Michael, L.; 34441 Camino El Molino, Capistrano Beach, CA 92624 (US). QUICK, Richard, L.; 32181 Fall River Road, Trabuco Canyon, CA 92679 (US).<br><br><b>(74) Agents:</b> KLEIN, Howard, J. et al.; Klein & Szekeres, LLP, Suite 700, 4199 Campus Drive, Irvine, CA 92612 (US).  |           | <b>(81) Designated States:</b> AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).<br><br><b>Published</b><br><i>Without international search report and to be republished upon receipt of that report.</i> |
| <b>(54) Title:</b> ELECTROSURGICAL BIOPSY DEVICE AND METHOD<br><br><b>(57) Abstract</b><br><br>An electrosurgical biopsy device includes a stylet and a cannula movably mounted on a base. The stylet has a shaft with a head at its distal end and a stylet ablation element extending distally from the head. The stylet shaft is disposed through the cannula for axial translation therein between withdrawn and extended positions. The cannula has an opening at its distal end and a cannula ablation element adjacent the opening. Both ablation elements are activatable with energy that ablates adjacent tissue. A translation mechanism controllably moves (a) the stylet between the withdrawn and extended positions and (b) the cannula between a proximal position and a distal position relative to the base. In use, with the stylet in the withdrawn position against the distal end of the cannula, and with the stylet ablation element activated, the stylet and the cannula are pushed through the skin and the underlying tissue until the stylet head is adjacent a targeted tissue mass. Next, the stylet is extended distally from the distal end of the cannula so that its head penetrates the tissue mass. The cannula ablation element is then activated, and the cannula is pushed through the tissue mass toward the stylet head, thereby cutting a "core" through the tissue mass that is captured as a tissue specimen within the distal end of the cannula. The cannula and the stylet are then removed from the patient's body. |           |  |

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1 ELECTROSURGICAL BIOPSY DEVICE AND METHOD

2  
3 CROSS-REFERENCE TO RELATED APPLICATIONS

4 Not Applicable

5  
6 FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

7 Not Applicable

8  
9 BACKGROUND OF THE INVENTION

10 The present invention relates to devices and methods for removing a  
11 sample of tissue from a human or animal. In particular, the present invention  
12 pertains to devices and methods for conducting a biopsy to remove a sample or  
13 specimen of a tumor or lesion for examination and analysis.

14 In diagnosing and treating certain medical conditions, such as  
15 potentially cancerous tumors, it may be desirable to extract from a portion of  
16 suspicious tissue, such as a tumor, a specimen of the suspicious tissue for  
17 detailed examination and analysis. The process of removing such a specimen  
18 of tissue is referred to as a biopsy.

19 In many instances, the suspicious tissue to be examined is inside the  
20 patient's body. For example, the suspicious tissue may be a tumor inside a  
21 human breast. To minimize surgical intrusion into the body, it is desirable to  
22 be able to insert a small instrument into the body for extracting a portion of the  
23 suspicious tissue.

24 Different types of instruments and procedures have been developed for  
25 conducting biopsies to extract a tissue specimen for analysis. One device that  
26 has been developed is the fine needle aspirator. This device comprises a  
27 hollow needle, the end of which is sharpened. The needle is inserted into the  
28 suspicious tissue so that individual cells or clusters of cells of the tissue lodge

1 inside the hollow core of the needle. The needle is then extracted from the  
2 patient, and the cells and fluid removed from the needle for a cytological  
3 examination. In certain circumstances, however, it may be desirable to extract  
4 portions of tissue for a histological examination, a procedure that is not  
5 typically feasible using a fine needle aspirator.

6 Another type of tissue-sampling device for biopsies is exemplified by  
7 the device described in U.S. Patent No. Re.34,056 - Lindgren et al. This type  
8 of device includes a forward stylet, which includes at its distal end a sharpened  
9 cutting surface. The stylet may be, for example, a needle sized between 12  
10 and 20 gauge. Behind the sharpened cutting end of the stylet, along the shaft  
11 thereof, is a groove. A hollow cannula surrounds the stylet, and has its distal  
12 end sharpened to form a fine cutting edge. A mechanism is provided to move  
13 the stylet and the cannula forward separately. For example, springs may be  
14 used for this purpose. Preferably, the stylet and the cannula are moved  
15 forward rapidly so that the sharpened ends thereof may efficiently cut the  
16 tissue. In operation, the operator of this type of device first causes the stylet to  
17 be pushed forward through the tumor or suspect tissue. After the distal end of  
18 the stylet has passed through the suspect tissue, a portion of the tissue  
19 surrounding the stylet partially fills the groove on the shaft of the stylet. The  
20 cannula is then pushed forward so that the sharpened distal end of the cannula  
21 cuts off the portion of the tissue that has filled the groove on the shaft of the  
22 stylet, and encloses that tissue. The entire device may then be removed from  
23 the patient's body, and the tissue trapped in the cannula removed for  
24 examination and analysis.

25 U.S. Patent No. 5,526,822 - Burbank et al. discloses another type of  
26 biopsy device that includes the ability to apply a vacuum to the groove in the  
27 stylet. This vacuum assists in drawing tissue into the groove, ensuring that a  
28 more substantial portion of tissue is severed by the cutting cannula. Using

1 such a system, it is in some cases possible to use a relatively large stylet (e.g.,  
2 a 7 to 14 gauge needle) to obtain a relatively large tissue sample.

3 All of the above-described systems use knife edges to cut the tissue.  
4 The cutting edge must remain extremely sharp, so that it cuts the tissue  
5 cleanly. Moreover, the stylet and the cannula cutter must be propelled forward  
6 rapidly to provide a clean cut through the tissue. Elaborate mechanisms are  
7 typically employed to provide the rapid forward movement. Because the  
8 knife edges move rapidly, however, there is limited time for tissue to fill the  
9 groove on the stylet. Therefore, the system sometimes obtains a smaller  
10 sample than would be ideal. In addition, variations in tissue density and  
11 anatomy may cause the stylet to deflect from its ideal position in relation to the  
12 tissue to be penetrated.

13 Electrosurgical techniques have been used in a variety of  
14 circumstances, including certain types of biopsies. In electrosurgery, high  
15 frequency electrical energy is applied through a primary electrode to tissue.  
16 The electrical energy flows through the tissue to a return electrode. The tissue  
17 adjacent to the primary electrode is ablated, to form an opening in the tissue.  
18 The return electrode in monopolar electrosurgery may be a large electrode  
19 placed on the exterior of the patient's body at a point remote from the primary  
20 electrode. In bipolar electrosurgery, the return electrode may be a smaller  
21 electrode positioned somewhat near the primary electrode. An exemplary  
22 biopsy instrument using electrosurgical techniques is described in International  
23 Publication No. WO 98/08441.

24

## 25 SUMMARY OF THE INVENTION

26 The present invention, in one aspect, is a novel electrosurgical tissue  
27 sampling device, or biopsy device, including a novel electrosurgical stylet. In  
28 another aspect, the present invention is a method of using the novel biopsy

1 device to obtain a tissue specimen.

2 The novel stylet of the present invention includes a shaft that has a  
3 proximal end and a distal end. At the distal end of the stylet shaft is a  
4 substantially hemispherical head. A stylet electrode extends distally from the  
5 stylet head. The stylet electrode may be activated with radio frequency (RF)  
6 electrical energy to ablate the tissue adjacent the stylet electrode. A cannula  
7 that cooperates with the stylet also has a proximal end and a distal end. An  
8 opening is formed at the distal end of the cannula. The distal end of the  
9 cannula may be selectively separated from the stylet, or may abut the stylet to  
10 close the opening at the distal end of the cannula. Also at the distal end of the  
11 cannula is another electrode that also may be activated with radio-frequency  
12 electrical energy to ablate the tissue adjacent the distal end of the cannula.

13 The system may be monopolar, in which the return electrical path is  
14 provided by a return electrode attached to the patient's body remote from the  
15 device. Alternatively, the system may be bipolar, in which the return electrical  
16 path is provided by a return electrode on the device itself. The same return  
17 electrical path may be used for both the electrode on the stylet and the  
18 electrode on the cannula.

19 In accordance with the method of the present invention, the electrode  
20 on the head of the stylet is energized. With the stylet in a withdrawn position  
21 abutting against the distal end of the cannula, the stylet and the cannula are  
22 pushed through the skin and the underlying tissue, while applying an RF  
23 current, until the head of the stylet is adjacent a targeted tissue mass (e.g., a  
24 lesion or tumor). Next, the stylet is extended distally from the distal end of the  
25 cannula so that its head penetrates the targeted tissue mass, whereby the stylet  
26 head and the distal end of the cannula are on opposite sides of the tissue mass.  
27 The electrode at the distal end of the cannula is then energized, and the  
28 cannula is pushed through the tissue mass toward the stylet head, thereby

1 cutting a "core" through the tissue mass that is captured as a tissue specimen  
2 within the distal end of the cannula. The cannula and the stylet are then  
3 removed from the patient's body. After the cannula and the stylet have been  
4 removed, they may be separated from one another, and the tissue specimen  
5 enclosed within the cannula may be removed and examined.

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#### 7 BRIEF DESCRIPTION OF THE DRAWINGS

8 Figure 1 is a perspective view of a preferred embodiment of a biopsy  
9 device constructed in accordance with the present invention;

10 Figure 1A is a perspective view of a portion of the cannula and stylet of  
11 a modified form of the preferred embodiment of the biopsy device;

12 Figure 2 is a distal end view of the device illustrated in Figure 1, taken  
13 from the left side of Figure 1;

14 Figure 3 is a perspective view, partially broken away, of a preferred  
15 embodiment of an electrosurgical stylet constructed in accordance with an  
16 aspect of the present invention, and incorporated in the device illustrated in  
17 Figure 1;

18 Figure 4 is a top view of the device of Figure 1, with the device set to  
19 begin a biopsy procedure in accordance with the method of the present  
20 invention;

21 Figure 5 is a second top view, similar to the view of Figure 4, of the  
22 device of Figure 1, with the stylet extended for an intermediate step of a  
23 biopsy procedure in accordance with the method of the present invention;

24 Figure 6 is a third top view, similar to the view of Figure 4, of the  
25 device of Figure 1, with both the stylet and the cannula extended for a further  
26 stage of a biopsy procedure in accordance with the method of the present  
27 invention;

28 Figure 7 is a cross-sectional view taken along line 7-7 of Figure 6;

1           Figure 8 is a cross-sectional view taken along line 8 - 8 of Figure 6;  
2           Figure 9 is a staggered cross-sectional view taken along line 9 - 9 of  
3   Figure 4;  
4           Figure 10 is a cross-sectional view taken along line 10 - 10 of Figure 9;  
5           Figure 11 is a cross-sectional view taken along line 11 - 11 of Figure  
6   10;  
7           Figure 12 is a cross-sectional view of the cannula and stylet, taken  
8   along line 12 - 12 of Figure 6;  
9           Figure 13 is a view taken along line 13-- 13 of Figure 5, showing a  
10   distal end view of the cannula, and a cross-sectional view of the stylet shaft;  
11           Figure 14 is a cross-sectional view taken along line  
12   14 - 14 of Figure 12;  
13           Figure 15 is a cross-sectional view of the base of the biopsy device,  
14   taken along line 15 - 15 of Figure 7;  
15           Figure 16 is a side elevational view of an alternative embodiment of the  
16   electrosurgical stylet that may be incorporated in the biopsy device of the  
17   present invention;  
18           Figure 17 is a perspective view of an alternative embodiment of the  
19   cannula portion of the biopsy device of the present invention;  
20           Figure 18 illustrates the step of inserting the biopsy device into tissue  
21   for extracting a tissue specimen, in accordance with the method of the present  
22   invention;  
23           Figure 19 illustrates the biopsy device positioned to begin extracting a  
24   tissue specimen in accordance with the method of the present invention;  
25           Figure 20 illustrates the biopsy device at an intermediate step of the  
26   biopsy procedure in accordance with the method of the present invention; and  
27           Figure 21 illustrates the biopsy device at a later intermediate step of the  
28   biopsy procedure in accordance with the method of the present invention.



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## DETAILED DESCRIPTION OF THE INVENTION

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Referring first to Figure 1, a particular preferred embodiment of a biopsy device 100, constructed in accordance with the present invention, is illustrated. The biopsy device 100 includes a probe 102, a base unit 104, an energy source, such as a radio-frequency generator 106, and a control unit 108.

The probe 102 includes a stylet 110 and a cannula 112. The stylet 110 electrosurgically separates tissue through the use of an electrical current activated at high frequency, such as a frequency in the radio frequency range. The stylet 110, when electrically activated, ablates tissue adjacent its electrically active components.

The stylet 110, comprising an aspect of the present invention, is shown in Figure 3. The stylet 110 includes a stylet head 122 having a substantially cylindrical body with a substantially hemispherical surface at the distal end of the stylet head 122. The stylet head 122 is formed of an electrically insulating material, such as a plastic. The stylet head 122 is attached to the distal end of a stylet shaft 124, which is also formed of an electrically insulating material. The stylet shaft 124 may have a central longitudinal bore through it, preferably along the longitudinal axis of the shaft 124.

A conductive metal stylet electrode 126 protrudes distally from the stylet head 122. In the illustrated embodiment, the stylet electrode 126 is formed of an arcuate length of electrical conductor that protrudes from diametrically opposite sides of the stylet head 122, and extends over the hemispherical distal end surface of the stylet head 122. The radius of curvature for the stylet electrode 126 is substantially coplanar with the longitudinal axis of the stylet shaft 124. The stylet electrode 126 forms a first tissue ablation element for electrosurgically separating tissue so as to create an

1 incision.

2 For the purposes of the present description of the invention, the term  
3 "ablation", as used in this specification, is defined as the process of creating an  
4 incision by vaporizing tissue. The preferred embodiment described herein  
5 uses electrical energy in the radio frequency range for the ablation process.  
6 However, tissue ablation may also be accomplished with other energy sources,  
7 such as microwaves or ultrasound. In such cases, the configuration of the  
8 ablation elements may differ from the ablation electrodes described  
9 hereinbelow. The energy supply and control system may differ as well. The  
10 appropriate variations and modifications in these components to accommodate  
11 the alternative energy sources will suggest themselves to those skilled in the  
12 pertinent arts.

13 The stylet electrode 126 merges into a single stylet electrical conductor  
14 128 inside the stylet head 122. The single stylet electrical conductor 128  
15 extends through the central bore in the stylet shaft 124. The stylet conductor  
16 128 is electrically connected with both ends of the stylet electrode 126.

17 An alternative embodiment of the stylet head is illustrated in Figure 16.  
18 The embodiment illustrated in Figure 16 includes a conical head 130 that has  
19 an electrically conductive apex portion 132 that forms the stylet electrode.  
20 The apex portion is secured to the distal end of an insulative, frustum-shaped  
21 base portion 134. The conical stylet electrode 132, which forms the stylet  
22 tissue ablation element, is in electrical contact with the stylet conductor 128  
23 (as described above with reference to Figure 3).

24 The cannula 112 is formed of an elongated hollow outer tube 140  
25 (Figures 12, 13, and 14) that has a distal end and a proximal end. Preferably,  
26 the longitudinal axis of the cannula 112 coincides with the longitudinal axis of  
27 the stylet shaft 124. The outer tube 140 of the cannula 112 is formed of an  
28 electrically nonconductive or insulating material, such as plastic, and may be

1 formed by extrusion. For example, the outer tube 140 of the cannula may be  
2 formed of a polyimide. The outer surface of the cannula tube 140 may be  
3 coated with TEFLON® (polytetrafluoroethylene) or similar low-friction  
4 polymeric material to reduce sticking between the surface and the surrounding  
5 tissue.

6 At the distal end of the cannula 112 is a cannula electrode 142 forming  
7 a second tissue ablation element. The cannula electrode 142 may be formed of  
8 the distal end of a tubular conductor 144 extending along the length of the  
9 cannula 112, inside the outer tube 140.

10 An electrically insulating inner sleeve 146 may cover the inner surface  
11 of the tubular conductor 144. The inner cannula sleeve 146 may also be  
12 formed by extrusion of a polyimide. The inner surface of the inner cannula  
13 sleeve 146 may be coated with a low-friction polymeric material, such as  
14 TEFLON®. The inner insulating sleeve 146 is spaced from the stylet shaft  
15 124 to form an annular passage 148 that is open at the distal end of the cannula  
16 112. The annular passage 148 receives tissue samples that are severed by the  
17 cannula electrode 142, as described below.

18 In a bipolar configuration for the probe, described below, the cannula  
19 112 will include other elements 152, 156, shown in Figures 12, 13, and 14.  
20 These other elements, described below, are not incorporated in the monopolar  
21 configuration.

22 The stylet 110 and the cannula 112 may be moved relative one another  
23 along their common longitudinal axis. For example, the stylet 110 may be  
24 moved relative to the cannula 112 between an extended position in which the  
25 distal end of the stylet shaft 124 and the stylet head 122 are separated from the  
26 distal end of the cannula 112, and a withdrawn position in which the stylet  
27 head 122 abuts or is in close proximity to the distal end of the cannula 112.

28 Those familiar with electrosurgical techniques will understand that

1 when a high frequency electrical current is applied to a primary electrode, such  
2 as the stylet electrode 126, and the primary electrode is exposed to tissue, the  
3 tissue adjacent the primary electrode is ablated. To perform such  
4 electrosurgery, a return electrical path through the tissue is required, to close  
5 the electrical circuit.

6 An electrosurgical device may be either monopolar or bipolar. With a  
7 monopolar device, the return electrical path is provided through a return  
8 electrode that may be a grounded contact pad that is applied to the exterior of  
9 the patient's body at a point remote from where the primary electrode is placed  
10 in the body. With a bipolar device, the return electrical path is provided from  
11 the primary or ablation electrode through a return electrode that is located  
12 relatively near the primary electrode. The bipolar return electrode is contained  
13 on the same instrument body as the primary electrode. Although parts of the  
14 present invention are described with reference to a monopolar configuration,  
15 and parts are described with reference to a bipolar configuration, those skilled  
16 in the art will recognize how the device may be implemented in either  
17 configuration.

18 In the monopolar configuration of the biopsy device illustrated in  
19 Figure 1, a patient return pad 150 is attached to the patient's body, and is in  
20 electrical contact with the RF generator 106. The patient return pad 150 forms  
21 a return electrode for the energy delivered by the RF generator 106 to the  
22 stylet electrode 126 and the cannula electrode 142. In the monopolar  
23 configuration, the annular conductor 144 that terminates in the cannula  
24 electrode 142 is disposed between the external insulating layer of the tube 140,  
25 and the inner insulating sleeve 146.

26 A probe 102' used in the bipolar configuration of the biopsy device in  
27 accordance with the present invention is shown in Figure 1A. In the bipolar  
28 configuration, the return electrical path is provided through a conductor

1 contained within a bipolar cannula 112'. Referring to Figures 12, 13, 14, and  
2 1A, the additional elements of the bipolar cannula 112' are shown. A  
3 conductive layer 152 is contained just under the outer tube 140, and forms a  
4 return path electrode. A pair of diametrically-opposed longitudinal side  
5 openings or slots 154 (one of which is shown in Figure 1A) are provided in the  
6 outer tube 140. These side openings 154 may extend longitudinally along a  
7 substantial portion of the length of the cannula 112'. Through these openings  
8 154 in the outer tube 140, the conductive layer 152 forming the return path  
9 electrode is exposed to the environment surrounding the cannula 112'. Thus,  
10 when the probe 102' (Figure 1A) is inserted into a patient's tissue, the return  
11 electrode 140 is in contact with the tissue, and electrical current may flow  
12 through the tissue from the stylet electrode 126 and the cannula electrode 142  
13 to the return electrode 152. The return electrode is advantageously  
14 electrically connected to ground potential.

15 Referring now particularly to Figure 12, the annular cannula conductor  
16 144 in a bipolar implementation is spaced from the return path electrode 152  
17 by an insulating layer 156 of non-conductive material, such as plastic. The  
18 insulating layer 156 electrically isolates the return path electrode 152 from the  
19 cannula conductor 144.

20 When activated with a current oscillating at high frequency (such as in  
21 the radio frequency range), the cannula electrode 142 ablates tissue adjacent to  
22 the cannula electrode. As with the stylet electrode 126, the operation may be  
23 either monopolar or bipolar. For operation in accordance with a bipolar  
24 technique, the same return electrode 152 used with the stylet electrode 126  
25 may also be used in conjunction with the cannula electrode 142. However,  
26 those skilled in the art, taking the teaching provided herein, will also recognize  
27 that alternative electrical return paths may be provided.

28 An alternative embodiment of the cannula is illustrated in Figure 17.

1 This particular alternative embodiment is illustrated as a monopolar device.  
2 However, those skilled in the art will recognize that the illustrated embodiment  
3 may be modified to add a return electrode to implement a bipolar embodiment.  
4 In the alternative embodiment illustrated in Figure 17, the cannula is formed of  
5 a cannula body 160. A cannula conduit 162 extends along the length of the  
6 cannula body 160. A length of conductor extends through the cannula conduit  
7 162, and is formed into a substantially circular cannula electrode 164 that  
8 coincides with the distal end of the cannula body 160. Those skilled in the art  
9 will readily recognize that other configurations may be used to form the  
10 cannula electrode at the distal end of the cannula. For example, the cannula  
11 conduit 162 may be formed as a groove cut along the length of the cannula  
12 body 160. Similarly, the cannula conduit 162 may be formed on the interior  
13 surface of the cannula body 160.

14 An energy source, such as the radio-frequency generator 106, generates  
15 the electrical current required for application to the stylet electrode 126 and the  
16 cannula electrode 142. The design, construction, and operation of such a  
17 generator and control unit are conventional and well-understood by those  
18 familiar with electrosurgery technology.

19 The base unit 104 controls the position and movement of the stylet 110,  
20 the cannula 112, and the application of the electrical energy generated by the  
21 generator and control unit 106 to the stylet electrode 126 and the cannula  
22 electrode 142. The base unit 104 permits the cannula 112 and stylet 110 to be  
23 moved together, and also to be moved separately. For example, the probe 102,  
24 including both the stylet 110 and the cannula 112, may be moved between an  
25 extended position relative to the base unit 104 in which the distal end of the  
26 stylet 110 and the distal end of the cannula 112 are relatively farther from the  
27 base unit 104, and a withdrawn position in which the distal end of the stylet  
28 110 and the distal end of the cannula 112 are relatively closer to the base unit

1 104. Furthermore, the base unit 104 may extend the stylet 110 between an  
2 extended position relative to the cannula 112, and a withdrawn position  
3 relative to the cannula 112.

4 The base unit 104 may be enclosed in a housing 202 (shown in  
5 phantom lines in Figure 1). The housing 202 protects the internal elements of  
6 the device. The housing 202 may be substantially sealed to protect the internal  
7 elements of the base unit 104 from contamination during use of the stylet 110  
8 and cannula 112 during a biopsy procedure. However, the housing 202 may  
9 be selectively removable, or have an access panel (not shown) provided to  
10 allow access to certain elements within the base unit 104. In addition, the  
11 housing 202 may be shaped to facilitate hand holding of the device, or it may  
12 be configured to be attached to other devices (not shown) for holding the  
13 biopsy device in the proper position for conducting the biopsy procedure.

14 Referring now to Figures 1, 4, 5, and 6, the base unit 104 includes a  
15 base 204 to which is fixed an electric motor 206 (preferably a DC motor  
16 powered by a power supply 207). The motor 206 is employed for moving the  
17 stylet 110 and the cannula 112 relative to the base unit 104. A cannula carrier  
18 210 is slidably mounted on the base 204. The cannula 112 has a proximal end  
19 that is attached to a cannula carrier 210. The cannula carrier 210 translates the  
20 cannula 112 longitudinally on the base unit 104. The stylet shaft 124 has a  
21 proximal end that is attached to a stylet carrier 220 that is slidably mounted on  
22 the base 204. The stylet carrier 220 translates the stylet 110 longitudinally on  
23 the base 204. In combination with the cannula carrier 210, the stylet carrier  
24 220 also translates the stylet 110 relative to the cannula 112. The motor 206  
25 includes a drive shaft 221 to which is attached a drive screw 222. The drive  
26 screw 222 is threaded through a screw-driven slide 224 that moves the cannula  
27 carrier 210 and the stylet carrier 220 in the manner described below.

28 The stylet 110 and the cannula 112 are preferably separable from the

1 stylet carrier 220 and the cannula carrier 210, respectively. In this way, the  
2 entire probe unit 102, including the stylet 110 and cannula 112, may be  
3 replaced upon each use, without having to replace the entire device. This  
4 allows the stylet 110 and cannula 112 to be disposable, so that a new, sterile  
5 stylet and cannula may be used for each biopsy procedure.

6 The proximal end of the stylet 110 may be embedded in or attached to a  
7 stylet foot 225, formed of an electrically insulating material, such as plastic.  
8 The stylet foot 225 is removably mounted in the stylet carrier 220. For  
9 example, the stylet foot 225 may fit into a correspondingly shaped recess in  
10 the stylet carrier 220. A stylet retention strip 227, having its two ends  
11 removably attached to the stylet carrier 220, and extending across the top of  
12 the stylet foot 225, retains the stylet foot 225 in the stylet carrier 220.

13 Similarly, the proximal end of the cannula 112 may be embedded in or  
14 attached to a cannula foot 229, formed of an electrically insulating material,  
15 such as plastic. The cannula foot 229 is removably mounted in the cannula  
16 carrier 210, such as by being retained in a correspondingly shaped recess in the  
17 cannula carrier 210. A cannula retention strip 231, having its two ends  
18 removably attached to the cannula carrier 210, and extending across the  
19 cannula foot 229, retains the cannula foot 229 in the cannula carrier 210.

20 The entire probe unit 102, including the stylet 110 and the cannula 112  
21 may be made available to medical doctors and hospitals as a single modular  
22 unit, ready for attachment to the base unit 104. In this way, the sterility of the  
23 probe unit 102 may be maintained. After completion of a biopsy procedure,  
24 the entire probe unit 102 may then be removed from the base unit 104 and  
25 discarded in accordance with proper procedures for medical waste.

26 An exemplary mounting for the cannula carrier 210 on the base 204 is  
27 illustrated in Figure 7. The base 204 includes substantially U-shaped channels  
28 226 along each side thereof. Horizontal extensions 228 of the bottom portion



1 of the cannula carrier 210 engage these channels 226. The mounting of the  
2 cannula carrier 210 on the base 204 preferably provides very little friction  
3 between the cannula carrier 210 and the base 204. A low friction mounting  
4 helps to ensure smooth and accurate movement of the cannula carrier 210  
5 relative to the base 204.

6 The mounting of the stylet carrier 220 on the base 204 is  
7 advantageously similar to the mounting of the cannula carrier 210. An  
8 exemplary mounting for the stylet carrier 220 on the base 204 is illustrated in  
9 Figure 8. Horizontal extensions 230 of the bottom portion of the stylet carrier  
10 220 engage the U-shaped channels 226 formed in the base 204. The mounting  
11 of the stylet carrier 220 on the base 204 preferably provides very little friction  
12 between the stylet carrier 220 and the base 204. A low friction mounting helps  
13 to ensure smooth and accurate movement of the stylet carrier 220 relative to  
14 the base 204.

15 The base 204 includes a plurality of stops that define the maximum  
16 extent of the longitudinal movements of the cannula carrier 210 and the stylet  
17 carrier 220 along the base 204. In the particular embodiment illustrated, an  
18 end piece 232 is provided at the distal end of the base 204. The end piece 232  
19 forms a forward stop for the cannula carrier 210. An intermediate stop 234 is  
20 affixed to the base 204. The distal side of the intermediate stop 234 forms a  
21 rearward stop for the cannula carrier 210, while the proximal side of the  
22 intermediate stop 234 forms a forward stop for the stylet carrier 220. A back  
23 stop 236 is affixed to the base 204 as a rearward stop for the stylet carrier 220.

24 The cannula carrier 210 may be moved between a withdrawn position  
25 (illustrated in Figures 4 and 5) and an extended position (illustrated in Figure  
26 6). In the withdrawn position, the distal edge of the cannula carrier 210 is  
27 spaced from the end piece 232 of the base 204, and the proximal edge of the  
28 cannula carrier 210 abuts against the distal side of the intermediate stop 234.

1 In this withdrawn position, the cannula 112 is withdrawn relative to the base  
2 204. When the cannula carrier 210 is in the extended position, the distal edge  
3 of the cannula carrier 210 abuts against the end piece 232, and the cannula 112  
4 is extended distally with respect to the base 204. As the cannula carrier 210  
5 moves toward the distal end of the base 204, the cannula 112 moves distally  
6 with respect to the base 204. As the cannula carrier 210 moves toward the  
7 proximal end of the base 204, the cannula 112 moves proximally with respect  
8 to the base 204.

9 The stylet carrier 220 may also be moved between a withdrawn position  
10 (illustrated in Figure 4) and an extended position (illustrated in Figures 5 and  
11 6). In the withdrawn position, the distal edge of the stylet carrier 220 is spaced  
12 from the intermediate stop 234, and the proximal edge of the stylet carrier 220  
13 abuts against the back stop 236. In this withdrawn position, the stylet 110 is  
14 withdrawn relative to the base 204. When the stylet carrier 220 is in the  
15 extended position, the distal edge of the stylet carrier 220 abuts against the  
16 proximal side of the intermediate stop 234. As the stylet carrier 220 moves  
17 longitudinally on the base 204 toward the distal end of the base, the stylet 110  
18 moves distally with respect to the base 204. As the stylet carrier 220 moves  
19 longitudinally on the base 204 toward the proximal end of the base, the stylet  
20 110 moves proximally with respect to the base 204.

21 A drive mechanism on the base 204 moves the cannula carrier 210 and  
22 the stylet carrier 220. In the particular embodiment illustrated, the drive  
23 mechanism includes the electric motor 206, the drive screw 222, and the  
24 screw-driven slide 224. The screw-driven slide 224 is slidably mounted on the  
25 base 204 so as to be movable between a proximal position in which it is  
26 relatively near the motor 206, and a distal position in which it is relatively  
27 remote from the motor 206, and nearer the distal end of the base 204. The  
28 movement of the screw-driven slide 224 controls the movement of the cannula

1 carrier 210 and the stylet carrier 220.

2 The screw-driven slide 224 is moved along the base 204 by the drive  
3 screw 222, which in turn is driven by the motor 206 by means of the drive  
4 shaft 221. The motor 206 rotates the drive shaft 221 and the screw 222, the  
5 latter engaging threads (not shown) in the screw-driven slide 224 to move the  
6 screw-driven slide 224 along the base 204. When the motor 206 rotates in a  
7 first direction (for example, clockwise), the motor turns the drive screw 222 in  
8 the same direction, which in turn moves the screw-driven slide 224 from its  
9 proximal position toward its distal position. When the motor 206 rotates in the  
10 opposite direction, the rotation of the screw 222 moves the screw-driven slide  
11 224 in the opposite direction, toward its proximal position.

12 A pair of push rods 240 are fixed to the distal side of the screw-driven  
13 slide 224. Each of these push rods 240 extends through openings (not shown)  
14 in the stylet carrier 220, so that the distal ends of the push rods 240 may  
15 engage the proximal side of the cannula carrier 210. A spring bias is provided  
16 between the screw-driven slide 224 and the stylet carrier 220. This spring bias  
17 tends to maintain a specific predetermined separation between the screw-  
18 driven slide 224 and the stylet carrier 220. This spring bias may be provided  
19 by a pair of coil springs 242, each of which surrounds one of the push rods  
20 240.

21 The mechanical operation of the base unit 104 will now be described  
22 with reference to Figures 4, 5, and 6. Referring first to Figure 4, the biopsy  
23 device is illustrated in a configuration in which it is set to begin a biopsy  
24 procedure. The stylet 110 is withdrawn relative to the cannula 112 so that the  
25 stylet 124 abuts against the distal end of the cannula 112. The cannula 112  
26 and stylet 110 are both withdrawn to the full extent possible relative to the  
27 base 204; that is, they are at their respective proximal limits of travel relative  
28 to the base 204.

1           As the motor 206 is operated, it turns the screw 222, which moves the  
2 screw-driven slide 224 toward the distal end of the base 204 in the manner  
3 described above. The springs 242 between the screw-driven slide 224 and the  
4 stylet carrier 220 maintain the predetermined spacing between the screw-  
5 driven slide 224 and the stylet carrier 220, thus causing the stylet carrier 220 to  
6 move toward the distal end of the base 204 at approximately the same rate as  
7 the screw-driven slide 224. However, the cannula carrier 210 remains in its  
8 original position. Thus, the stylet 110 extends distally relative to the cannula  
9 112, so that the stylet head 122 separates from the distal end of the cannula  
10 112. This continues until the distal ends of the push rods 240 contact the  
11 proximal side of the cannula carrier 210, as illustrated in Figure 5. At this  
12 stage, the stylet head 122 is spaced from the distal end of the cannula 112,  
13 forming a gap between the proximal end of the stylet head 122 and the distal  
14 end of the cannula 112.

15           Also at this stage, the distal side of the stylet carrier 220 contacts the  
16 proximal side of the intermediate stop 234, blocking further movement of  
17 these stylet carrier 220 toward the distal end of the base 204. As the motor  
18 206 continues to rotate the drive screw 222, it continues to move the screw-  
19 driven slide 224 toward the distal end of the base 204. However, further  
20 movement of the stylet carrier 220 is blocked. As the spring bias provided by  
21 the springs 242 is overcome, the springs 242 compress, and the screw-driven  
22 slide 224 moves closer to the stylet carrier 220. As the screw-driven slide 224  
23 moves closer to the stylet carrier 220, the push rods 240 extend from the distal  
24 side of the stylet carrier 220 and engage the proximal side of the cannula  
25 carrier 210. As the screw-driven slide 224 continues to move toward the distal  
26 end of the base 204, the push rods 240 move the cannula carrier 210 toward  
27 the distal end of the base 204. This forward (distal) movement of the cannula  
28 carrier 210 moves the cannula 112 relative to the stylet 110, closing the gap

1 between the stylet head 122 and the distal end of the cannula 112, so that the  
2 stylet 110 is withdrawn relative to the cannula 112.

3 When the distal end of the cannula 112 contacts the proximal end of  
4 stylet head 122 (as illustrated in Figure 6), further forward (distal) movement  
5 of the cannula carrier 210 should be stopped. Forward movement of the  
6 cannula carrier 210 toward the distal end of the base 204 may be stopped by  
7 stopping the motor 206. The components of the device, including the base 204  
8 and the stops 232, 234, 236, may also be dimensioned so that at that point the  
9 distal side of the cannula carrier 210 contacts the end piece 232 of the base to  
10 stop further movement of the cannula carrier 210 in the distal (forward)  
11 direction.

12 As noted previously, the energy for the stylet electrode 126 and the  
13 cannula electrode 142 is supplied by the RF generator 106. Furthermore, the  
14 control of activation of the electrodes 126, 142, as well as control of the motor  
15 206 that moves the cannular carrier 210 and the stylet carrier 220, is provided  
16 by the control unit 108. Accordingly, electrical paths must be provided to  
17 conduct energizing current through the base unit 104 from the RF generator  
18 106 to the stylet electrode 126 and the cannula electrode 142, and to conduct  
19 control signals from the control unit 108 to the motor 206. (Control signals  
20 are also sent from the control unit 108 to the RF generator 106 to control the  
21 activation of the electrodes 126, 142.) In addition, a return electrical path must  
22 be provided for the patient return pad 150 (monopolar configuration) or the  
23 return electrode 152 (bipolar configuration).

24 Referring now to Figure 15, the base 204 includes a plurality of  
25 electrical connectors 260a, 260b, 260c, 260d for providing electrical  
26 connection to the RF generator 106 and the control unit 108, and to the power  
27 supply 207 for the motor 206. A stylet lead 262, a cannula lead 264, and (in a  
28 bipolar configuration only) a return lead 266 each have a first end that is

1 internally connected to separate ones of the connectors 260a-d. The other end  
2 of the stylet lead 262 is connected to a stylet base contact 268 that is fixed with  
3 respect to the base 204. For example, the stylet base contact 268 may be  
4 embedded in the intermediate stop 234. Similarly, the other end of the cannula  
5 lead 264 is connected to a cannula base contact 270 that is fixed with respect  
6 to the base 204. For example, the cannula lead contact 264 may be embedded  
7 in the base end piece 232.

8       The return lead 266 is included only in the bipolar configuration. It is  
9 not necessary in the monopolar configuration that includes the remote patient  
10 return pad 150 (Figure 1). In the monopolar configuration, the connection  
11 between the patient return pad 150 and the RF generator and control unit 106  
12 may be provided externally to the base unit 104. The return lead 266 in the  
13 bipolar configuration may be connected to a cannula return base contact 272  
14 that is fixed with respect to the base 204. For example, the return base contact  
15 272 may also be embedded in the base end piece 232.

16       Referring next to Figure 9, the structure of the proximal ends of the  
17 stylet 110 and the cannula 112, and the electrical paths for the stylet conductor  
18 128 and for the cannula conductor 144, are illustrated. Referring first to the  
19 electrical path for the stylet 110, the stylet base contact 268 is provided in the  
20 intermediate stop 234. A stylet wire 274 provides an electrical current path  
21 between the stylet base contact 268 and a stylet carrier contact 276 on the  
22 stylet carrier 220. Because the position of the stylet carrier 220 changes with  
23 respect to the intermediate stop 234, the stylet wire 274 should be able to  
24 accommodate changes in the physical separation between the stylet carrier 220  
25 and the intermediate stop 234 while maintaining a connection between the  
26 stylet base contact 268 and the stylet carrier contact 276. For example, the  
27 stylet wire 274 may be a coiled wire wrapped around a longitudinal pin 278.  
28 An opening 279 may be provided in the distal side of the stylet carrier 220 to

1 accommodate the coiled stylet wire 274.

2 The stylet carrier contact 276 remains in contact with an extension  
3 portion 280 of a stylet carrier terminal 282 that is mounted in the stylet foot  
4 225. The stylet carrier terminal 282, in turn, is in electrical contact with the  
5 stylet electrical conductor 128 (see Figures 12 and 13) that is enclosed in the  
6 stylet shaft 124. The stylet carrier terminal extension portion 280 may be  
7 formed as a spring to help maintain contact between the stylet carrier terminal  
8 extension portion 280 and the stylet carrier contact 276. The stylet carrier  
9 terminal 282 (with the extension portion 280) is fixed within the stylet foot  
10 225, so that when the stylet foot 225 is removed from the stylet carrier 220, the  
11 stylet carrier terminal 282 (with the extension portion 280) is removed with the  
12 stylet foot 225. The extension portion 280 fits through an opening in the stylet  
13 carrier 220 so that the extension portion may contact the stylet carrier contact  
14 276.

15 A similar type of electrical path is provided for the cannula conductor  
16 142 that is contained in the cannula 112. A cannula carrier terminal 286 is  
17 fixed within the cannula foot 229, which is removably mounted in the cannula  
18 carrier 210, as previously described. The cannula carrier terminal 286 is in  
19 electrical contact with the cannula conductor 144 that is enclosed within the  
20 cannula tube 140. (See also Figure 10.) The cannula carrier terminal 286 has  
21 a spring extension portion 288 that is in contact with a cannula carrier contact  
22 290 when the cannula foot 229 is mounted in the cannula carrier 210. A  
23 cannula wire 292 provides an electrical current path between the cannula  
24 carrier contact 290 with the cannula base contact 270 that is embedded in the  
25 base end piece 232. Again, because the position of the cannula slide 210  
26 changes with respect to the base end piece 232, the cannula wire 292 is  
27 advantageously a coiled wire wrapped around a longitudinal pin 294.

28 A series of electrical contacts and electrical wires substantially similar

1 to those for providing the electrical current path for the cannula conductor 144  
2 may be provided in the bipolar configuration in which a return electrode 152 is  
3 included in the cannula 112. For example, the return electrical path may be  
4 included on the opposite side of the cannula carrier 220 for providing contact  
5 between the cannula return electrode 152 and the return base contact 272 that  
6 is embedded in the base end piece 232. A return electrode 298 embedded in  
7 the electrically insulating cannula foot 229 (Figures 10 and 11) provides a  
8 portion of such electrical contact. A coiled return wire 302 (Figures 4 and 5)  
9 provides an electrical current path between the return electrode 298 and the  
10 return base contact 272 embedded in the base end piece 232. The coiled return  
11 wire 302 may be wrapped around a supporting longitudinal pin 304.

12 A method of performing a biopsy in accordance with an aspect of the  
13 present invention will be described with reference to Figures 18 through 21.  
14 Referring first to Figure 18, a portion of human tissue, such as a human breast  
15 410, is illustrated containing several tissue masses 420, which may be  
16 suspected tumors or lesions to be examined. Through an incision in the tissue  
17 410, the portion of the biopsy probe 102 containing the stylet 110 and the  
18 distal end of the cannula 112 is inserted, using RF current, until the stylet head  
19 122 is near a targeted tissue mass 420. The probe 102 is guided toward the  
20 targeted tissue mass 420 using conventional imaging techniques, such as  
21 ultrasound or X-rays. The stylet 110 and the cannula 112 are both in their  
22 withdrawn (proximal) positions, as illustrated in Figure 4. Insertion of the  
23 probe 102 toward the targeted tissue mass 420 may be assisted by energizing  
24 the stylet electrode 126 to ablate subcutaneous tissue between the skin and the  
25 targeted tissue mass 420. As shown in Figure 19, while the probe 102 is being  
26 inserted to access the targeted tissue mass 420, the stylet 110 is in its  
27 withdrawn position relative to the distal end of the cannula 112, so that stylet  
28 head 122 abuts or substantially abuts the distal end of the cannula 112, closing



1 the opening in the distal end of the cannula 112, and thus the passage 148.

2 The stylet electrode 126 is then electrically activated to ablate the tissue  
3 of the targeted tissue mass 420. The stylet head 122 is then pushed through  
4 the tissue mass 420, creating an opening through the tissue mass 420 as the  
5 stylet 110 penetrates the tissue mass by moving distally toward its extended  
6 position, while the cannula 112 remains in its proximal position, so that the  
7 stylet head 122 separates from the distal end of the cannula 112. A gap is thus  
8 opened between the stylet head 122 and the distal end of the cannula 112. A  
9 portion of the tissue mass 420 fills in this gap between the stylet head 122 and  
10 the cannula 112, around the stylet shaft 124. A particular advantage of the  
11 arcuate stylet electrode 126 is that it creates a narrow "slice" through the  
12 targeted tissue mass 420, thereby facilitating the filling of the aforesaid gap  
13 with the portions of the tissue mass on either side of the "slice" that collapse  
14 into the gap after being pushed outwardly by the passage of the stylet head  
15 122.

16 The stylet electrode 126 may then be deactivated, and the cannula  
17 electrode 142 activated. With the cannula electrode 142 activated, the portion  
18 of the tissue mass 420 adjacent the cannula electrode 142 is ablated, and the  
19 cannula 112 may be pushed forward through the portion of the tissue mass 420  
20 that has filled in around the stylet shaft 124. As the cannula 112 moves  
21 through the tissue mass 420, it cuts off a portion of the tissue mass 420, and  
22 encases that portion in the annular channel 148 within the cannula 112. Once  
23 the cannula 112 has closed the gap between the distal end of the cannula 112  
24 and the stylet head 122, the severed portion of the tissue mass 420 is contained  
25 within the annular channel 148 of the cannula 112. The entire probe 102 may  
26 then be removed from the tissue mass 420 and the patient's body. Once  
27 removed, the cannula 112 and the stylet 110 may again be separated, and the  
28 tumor portion contained within the annular channel 148 of the cannula 112

1 removed for examination and analysis.

2       Using the device and method of the present invention, the removal of  
3 tissue specimens may proceed at a slower pace than is typically possible using  
4 conventional spring-activated knife cutters. In particular, additional time can  
5 be allowed between the insertion of the stylet through the suspicious tissue,  
6 and the insertion of the annular cannula. This additional time allows more of  
7 the tissue to fill the space surrounding the stylet shaft 124, allowing the  
8 cannula electrode 142 to cut a larger sample of the suspicious tissue than has  
9 typically been possible using the cutters of the prior art. In addition, the stylet  
10 and cannula of the present invention are less likely to be deflected as they  
11 move through the tissue than are the mechanical cutters of prior art biopsy  
12 devices.

13       The specific embodiments described and illustrated above are  
14 exemplary, and not exhaustive or exclusive. Those familiar with the art will  
15 recognize that various modifications may be made to the specific embodiments  
16 described above without departing from the concepts of the present invention.  
17 For example, those skilled in the art will recognize that various modifications  
18 may be made to the base unit, and that different configurations may be used  
19 for controlling the movement and position of the stylet and the cannula. In  
20 addition, different specific shapes of the stylet, the stylet head, and cannula  
21 may be incorporated into a system implementing the present invention.  
22 Furthermore, although an electric motor is the preferred mechanism for  
23 driving the cannula carrier and the stylet carrier, other mechanisms, such as  
24 mechanical springs or pneumatic mechanisms, may be employed. Indeed, a  
25 simplified device may employ manually-driven carriers. Moreover, although  
26 RF energy is preferred to effect the tissue ablation, other types of energy (e.g.,  
27 microwave, ultrasound, or laser) may be employed instead, as mentioned  
28 above. These and other modifications and variations that may suggest

- 1 themselves are considered to be within the spirit and scope of the present
- 2 invention, as defined in the claims that follow.

## 1 WHAT IS CLAIMED IS:

2 1. An electrosurgical stylet, comprising:

3 a shaft having a proximal end and a distal end and defining a  
4 longitudinal axis therebetween;

5 a head fixed to the distal end of the shaft; and

6 a tissue ablation electrode extending distally from the head.  
78 2. The electrosurgical stylet of Claim 1, wherein the head has a  
9 substantially hemispherical distal surface, and wherein the tissue ablation  
10 electrode comprises an arcuate length of electrical conductor having a radius  
11 of curvature that is substantially coplanar with the longitudinal axis of the  
12 shaft.  
1314 3. The electrosurgical stylet of Claim 1, wherein the head is  
15 substantially frustoconical having an apex portion, and wherein the electrode  
16 includes the apex portion.  
17

18 4. A biopsy device, comprising:

19 an elongate cannula tube having a distal and a proximal end;

20 a first tissue ablation element on the distal end of the cannula;

21 an elongate stylet disposed within the cannula for axial

22 translation therein between an extended position and a withdrawn

23 position and having a distal end; and

24 a second tissue ablation element on the distal end of the stylet.  
2526  
27 5. The biopsy device of Claim 4, wherein the stylet comprises:

28 a shaft having a proximal end and a distal end and defining a

1 longitudinal axis therebetween; and

2 a substantially hemispherical head fixed to the distal end of the  
3 shaft, the second tissue ablation element extending distally from the  
4 head.

5  
6 6. The biopsy device of Claim 5, wherein the first and second ablation  
7 elements are activated by radio frequency electrical current, and wherein the  
8 second ablation element comprises an arcuate length of electrical conductor  
9 having a radius of curvature that is substantially coplanar with the longitudinal  
10 axis of the shaft.

11

12 7. The biopsy device of Claim 4, wherein the stylet comprises:  
13 a shaft having a proximal end and a distal end and defining a  
14 longitudinal axis therebetween; and  
15 a conical head terminating in an apex portion, wherein the  
16 second tissue ablation element includes the apex portion.

17

18 8. The biopsy device of Claim 4, wherein the first and second tissue  
19 ablation elements are activatable by an energy source so as to effect tissue  
20 ablation.

21

22 9. The biopsy device of Claim 8, wherein the energy source is a radio  
23 frequency energy source.

24

25 10. The biopsy device of Claim 4, further comprising stylet translation  
26 means connected to the stylet for translating the stylet within the cannula  
27 between the withdrawn and extended positions.

28

1           11. The biopsy device of Claim 10, wherein the device includes a base,  
2 wherein the stylet has a proximal end extending proximally from the proximal  
3 end of the cannula, and wherein the translation means comprises:

4           a carrier connected to the proximal end of the stylet and movably  
5 mounted on the base, the carrier being movable on the base between a  
6 first position in which the stylet is in the withdrawn position and a  
7 second position in which the stylet is in the extended position; and  
8 carrier drive means, coupled to the carrier, for moving the carrier  
9 between the first and second positions.  
10

11           12. The biopsy device of Claim 11, wherein the carrier drive means is  
12 driven by a motor.  
13

14           13. The biopsy device of Claim 12, wherein the motor has a drive  
15 shaft, and wherein the carrier drive means comprises:

16           a drive screw coupled for rotation with the drive shaft;  
17 a screw-driven mechanism coupled between the drive screw and  
18 the carrier, whereby rotation of the drive screw in a first direction  
19 moves the carrier from the first position to the second position.  
20

21           14. A biopsy device, comprising:

22           a base having a proximal end and a distal end;  
23 an elongate cannula having an open distal end and an open  
24 proximal end mounted on the base for axial translation thereon between  
25 a proximal position and a distal position;  
26 an elongate stylet disposed substantially coaxially within the  
27 cannula, the stylet having a proximal end that extends proximally from  
28 the proximal end of the cannula and that is mounted on the base for

1 axial translation between a withdrawn position and an extended  
2 position with respect to the cannula, the stylet having a distal end;  
3 a first tissue ablation element on the distal end of the cannula;  
4 a second tissue ablation element on the distal end of the stylet;  
5 and

6 translation means for sequentially moving the stylet from its  
7 withdrawn position to its extended position, and then moving the  
8 cannula from its proximal position to its distal position.  
9

10 15. The biopsy device of Claim 14, wherein the translation means  
11 comprises:

12 a first carrier, connected to the proximal end of the stylet and  
13 slidably mounted on the base for translation thereon between a first  
14 position corresponding to the withdrawn position of the stylet and a  
15 second position corresponding to the extended position of the stylet;  
16 a second carrier, connected to the proximal end of the cannula  
17 and slidably mounted on the base between the first carrier and the distal  
18 end of the base, for translation thereon between a proximal position  
19 corresponding to the proximal position of the cannula and a distal  
20 position corresponding to the distal position of the cannula; and  
21 carrier drive means, engageable with the first and second  
22 carriers, for sequentially driving the first carrier from its first position to  
23 its second position and then driving the second carrier from its first  
24 position to its second position.  
25

26 16. The biopsy device of Claim 15, wherein the carrier drive means  
27 comprises:

28 a motor having a drive shaft;

1                   a drive screw coupled for rotation with the drive shaft;  
2                   a screw-driven mechanism coupled between the drive screw and  
3           the carrier, whereby rotation of the drive screw in a first direction  
4           moves the carrier from the first position to the second position.

5  
6           17. The biopsy device of Claim 14, wherein the first and second tissue  
7   ablation elements are activated by radio frequency electrical current.

8  
9           18. The biopsy device of Claim 15, wherein the stylet is removably  
10   mounted in the first carrier and the cannula is removably mounted in the  
11   second carrier.

12  
13          19. The biopsy device of Claim 14, wherein the stylet comprises:  
14                  a shaft having a proximal end and a distal end and defining a  
15          longitudinal axis therebetween; and  
16                  a substantially hemispherical head fixed to the distal end of the  
17          shaft, the second tissue ablation element extending distally from the  
18          head.

19  
20          20. The biopsy device of Claim 19, wherein the first and second  
21   ablation elements are energized by radio frequency electrical current, and  
22   wherein the second ablation element comprises an arcuate length of electrical  
23   conductor having a radius of curvature that is substantially coplanar with the  
24   longitudinal axis of the shaft.

25  
26          21. The biopsy device of Claim 17, wherein the first ablation element  
27   is an ablation electrode, and wherein the cannula includes a return electrode  
28   spaced from the ablation electrode.



1           22. The biopsy device of Claim 21, wherein the cannula includes an  
2 elongate aperture along a portion of its length, and wherein the return  
3 electrode comprises a length of conductor contained within the cannula, at  
4 least a portion of the conductor being exposed through the elongate aperture.

5

6           23. A method of taking a tissue sample from a targeted subcutaneous  
7 tissue mass within the body of a patient, comprising the steps of:

8                 providing a probe comprising a cannula having a distal end with  
9 a first tissue ablation element, and a stylet disposed coaxially within the  
10 probe for axial movement therein between a withdrawn position and an  
11 extended position relative to the distal end of the cannula, the stylet  
12 having a distal end with a second tissue ablation element;

13                 while activating the second ablation element with energy of a  
14 type and quantity that causes tissue ablation, advancing the probe by  
15 tissue ablation, with the stylet in the withdrawn position, into the  
16 patient's body toward the targeted tissue mass;

17                 with the second ablation element activated, moving the stylet to  
18 its extended position so that it penetrates the targeted tissue mass by  
19 ablation, while creating a gap between the second ablation element and  
20 the distal end of the cannula that fills with a portion of the tissue from  
21 the targeted tissue mass;

22                 while activating the first ablation element with energy of a type  
23 and quantity that causes tissue ablation, moving the cannula distally  
24 relative to the stylet so as to close the gap, thereby capturing the portion  
25 of the tissue mass within the cannula; and

26                 withdrawing the probe from the body with the portion of the  
27 tissue mass captured within the cannula.

28

1           24. The method of Claim 23, wherein the first and second ablation  
2 elements are activated with radio frequency electrical current.

3

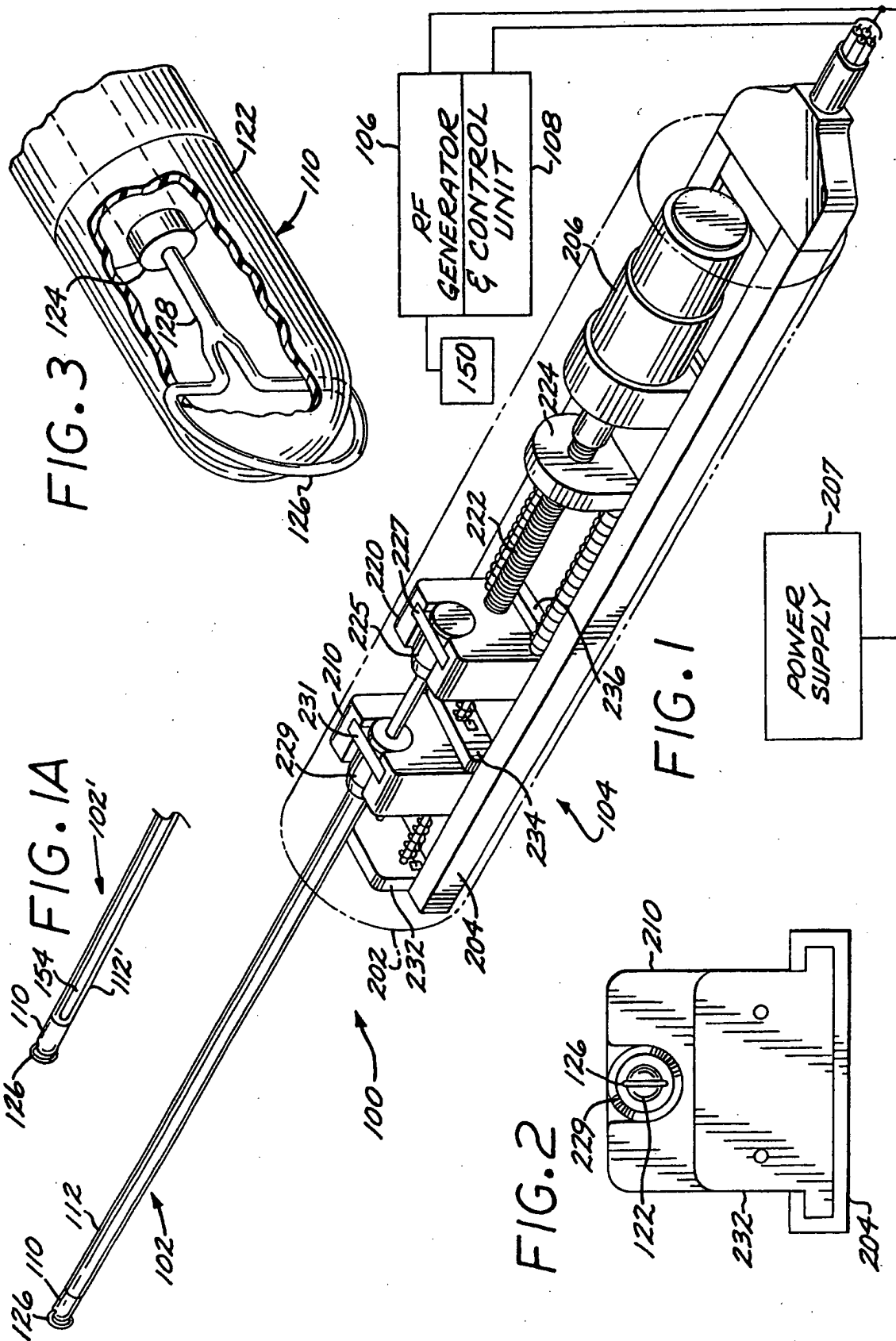
4           25. The method of Claim 23, wherein the stylet and the cannula are  
5 movably mounted on a base, wherein the cannula is movable between a  
6 proximal position and a distal position relative to the base, wherein the  
7 cannula is in the proximal position during the steps of advancing the probe and  
8 of moving the stylet, and wherein the step of moving the cannula includes the  
9 step of moving the cannula from its proximal position to its distal position.

10

11           26. The method of Claim 23, wherein the steps of moving the stylet  
12 and moving the cannula are performed by an electrically powered driving  
13 mechanism.

14

15           27. The method of Claim 23, wherein the step of moving the stylet  
16 creates a narrow slice through the targeted tissue mass.



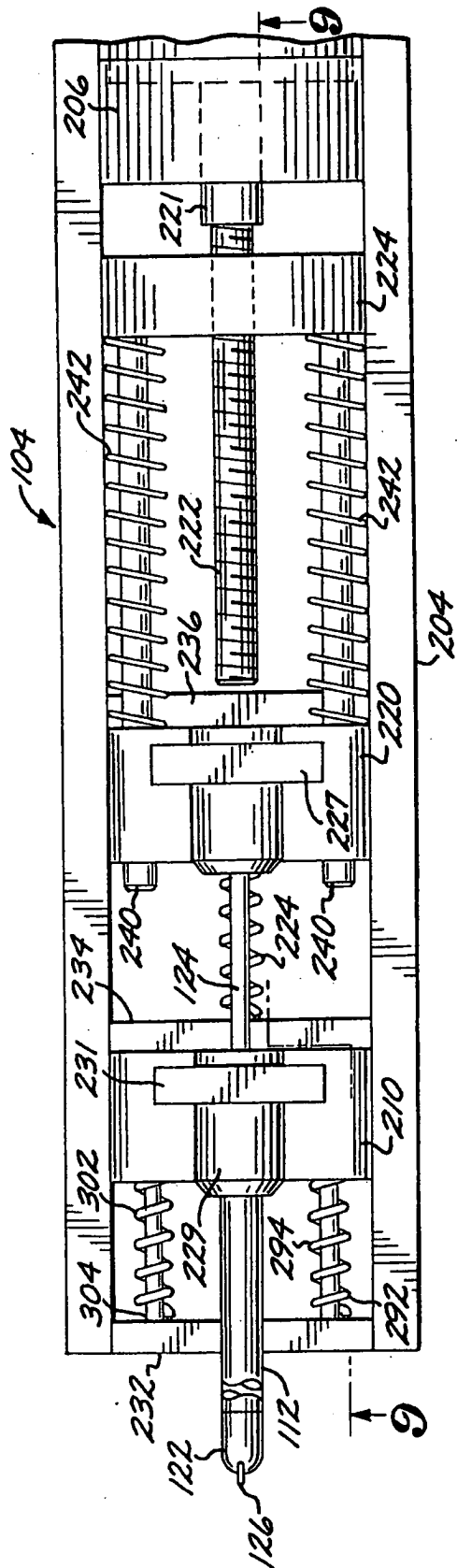


FIG. 4

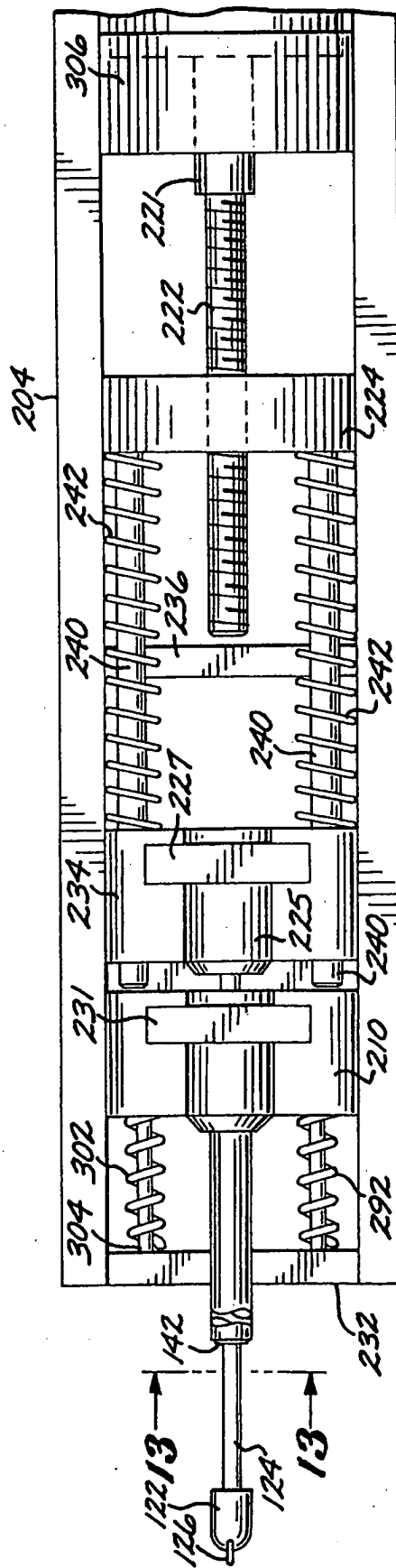


FIG. 5

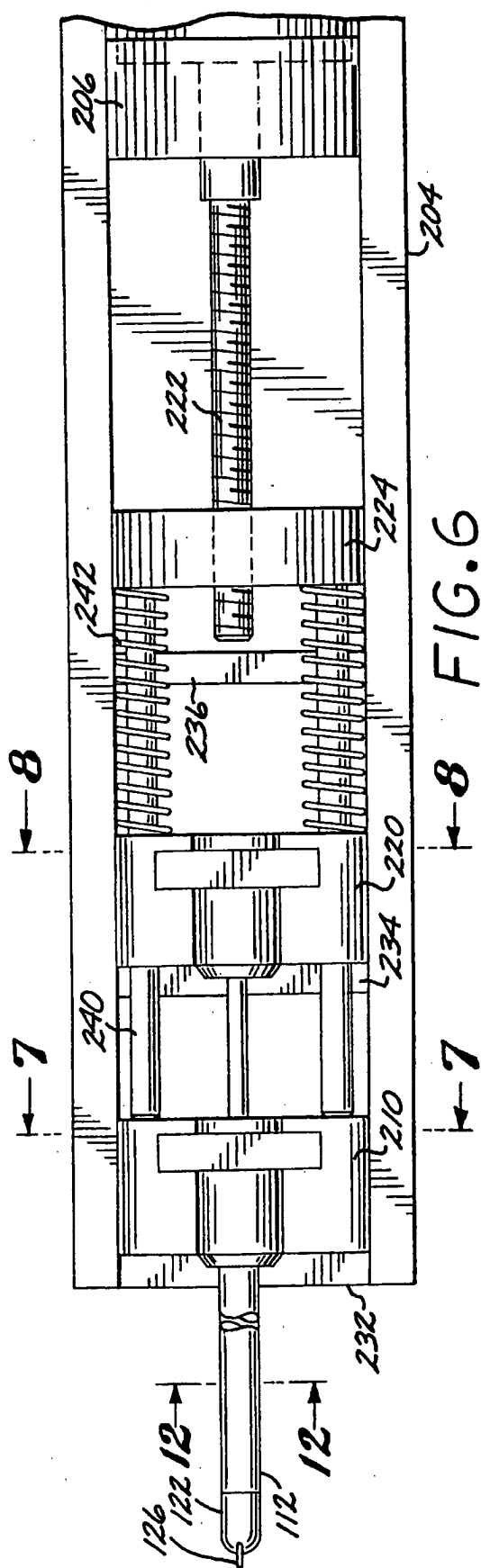
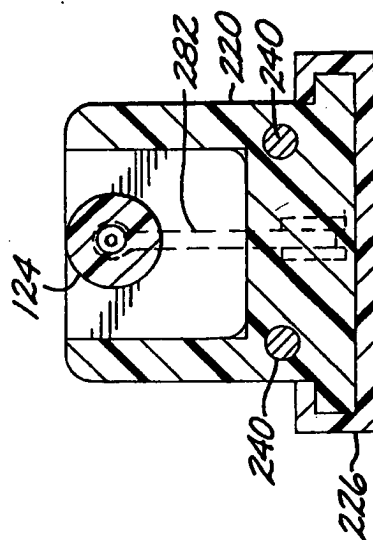


FIG. 6



F/G.8

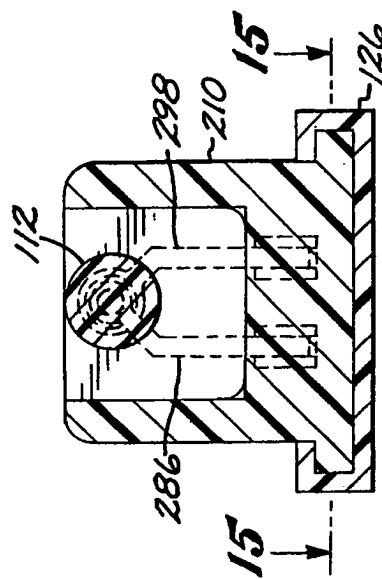
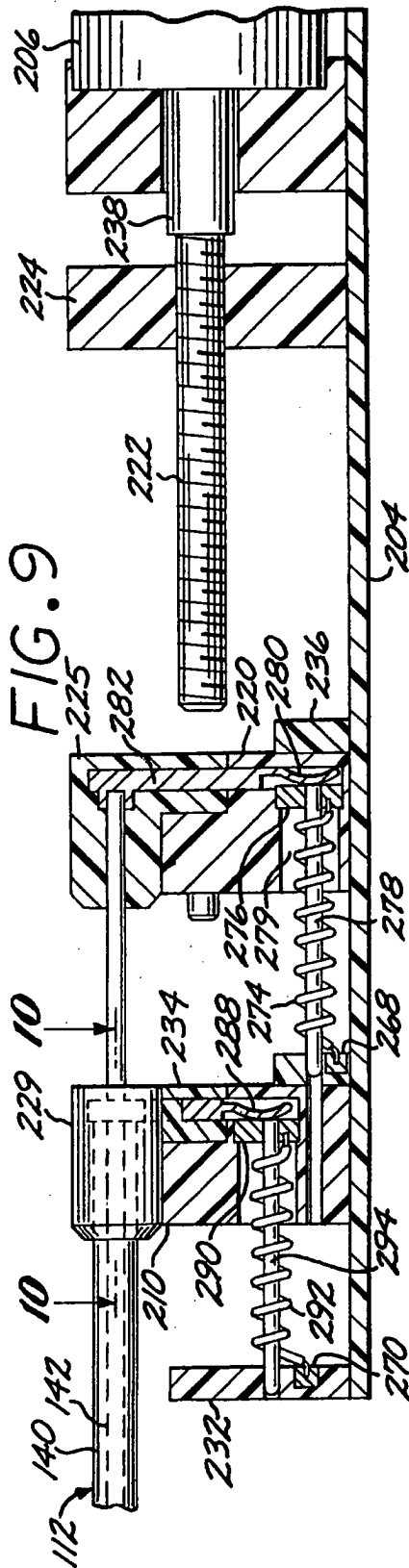
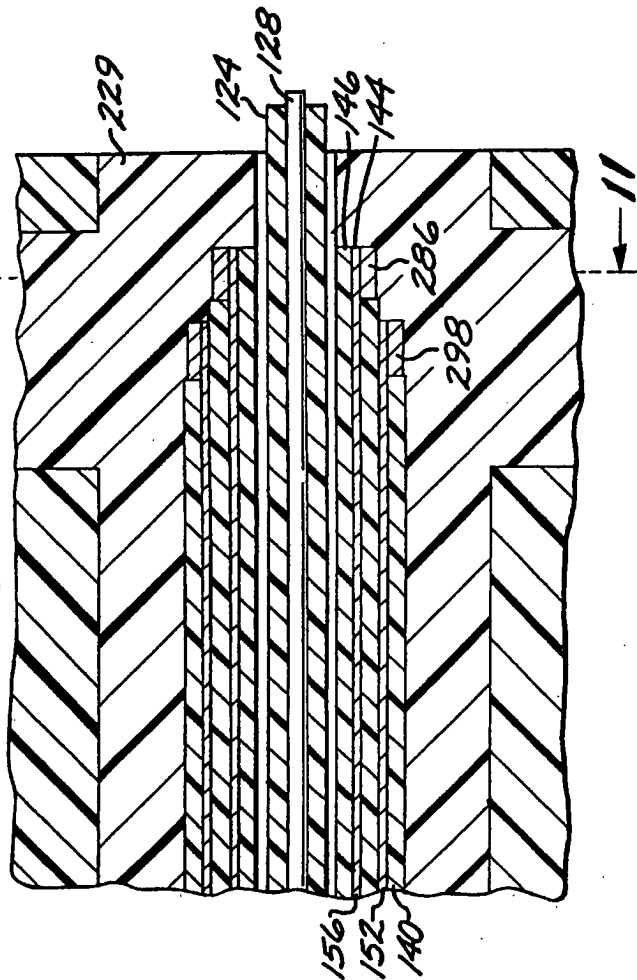


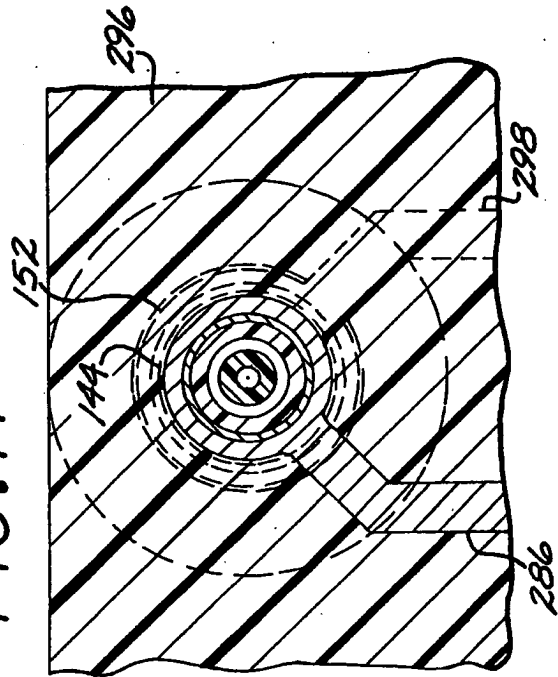
FIG. 7

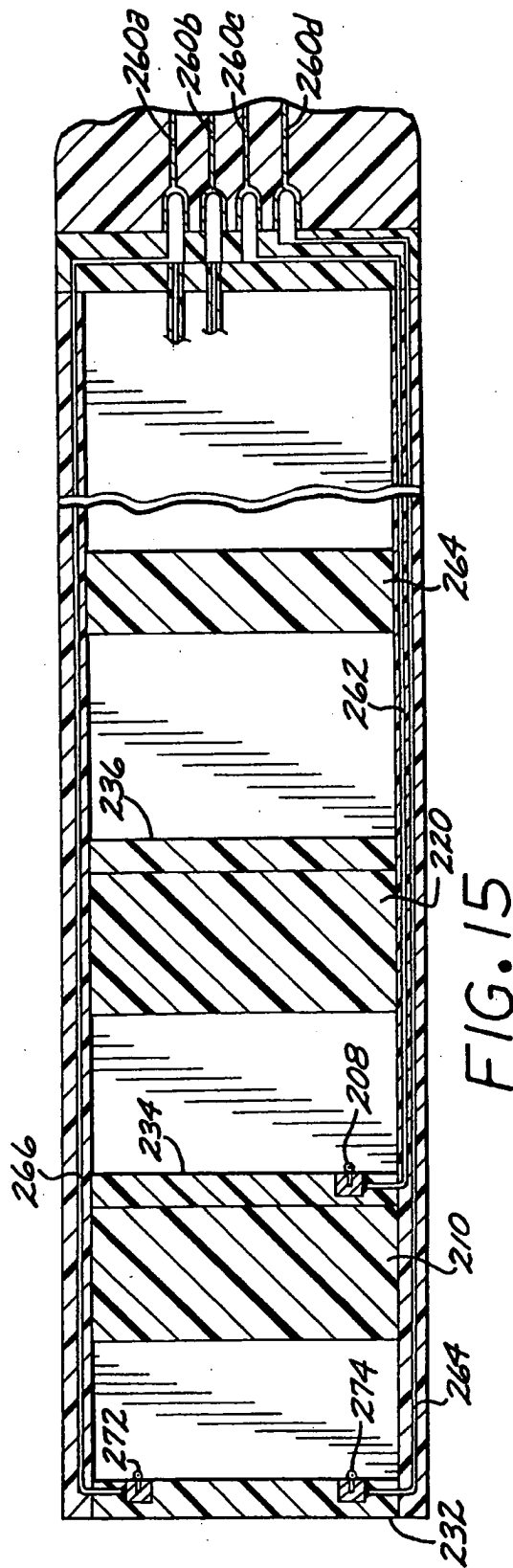
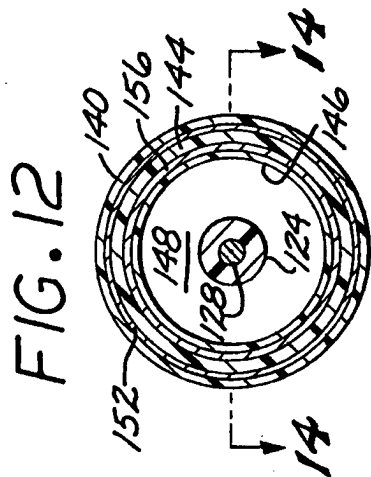
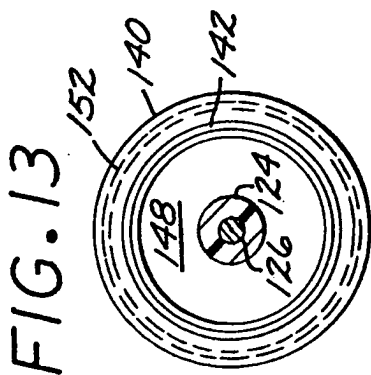
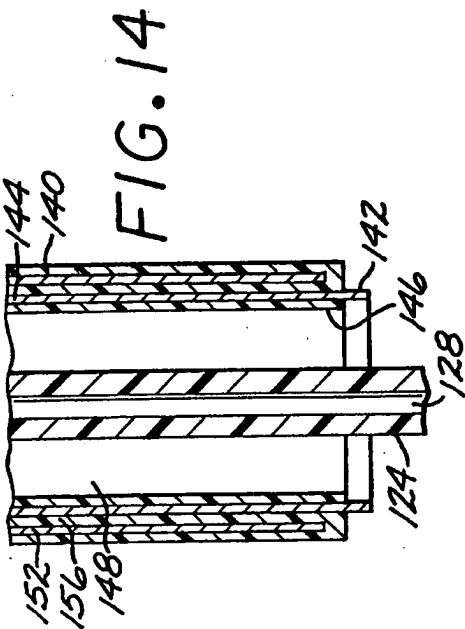


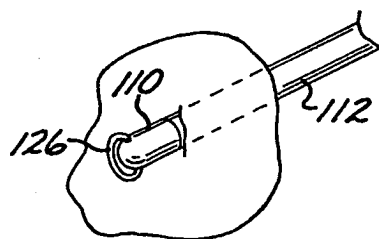
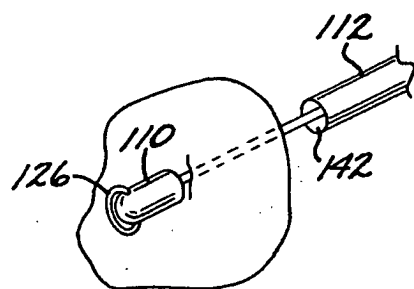
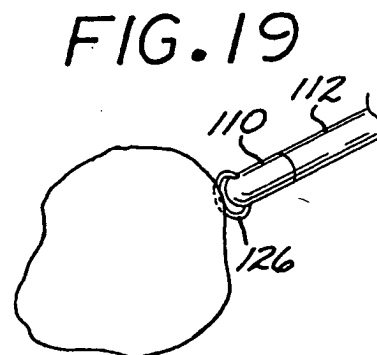
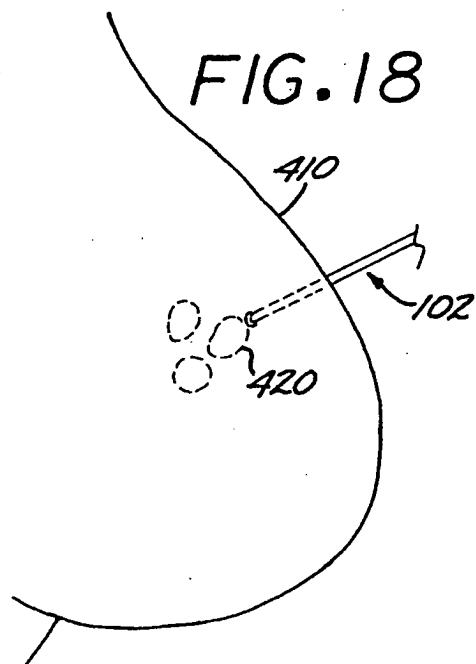
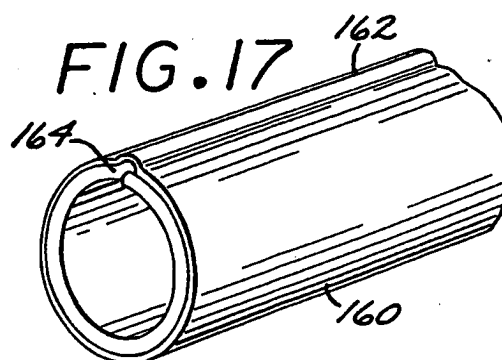
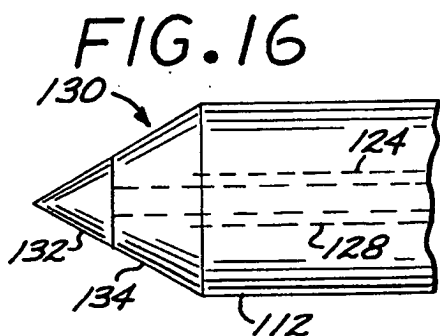
**FIG. 10**



**FIG. 11**











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|  |                  |  |
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| <b>(51) International Patent Classification:</b><br><b>A61B 18/14</b>  | <b>A3</b>        | <b>(11) International Publication Number:</b><br><b>WO 00/16697</b><br><b>(43) International Publication Date:</b><br>30 March 2000 (30.03.2000) |
| <b>(21) International Application Number:</b> PCT/US99/21416<br><b>(22) International Filing Date:</b> 17 September 1999 (17.09.1999)<br><b>(30) Priority Data:</b><br>09/159,467 23 September 1998 (23.09.1998) US<br><b>(60) Parent Application or Grant</b><br>SENORX, INC. [/]; O. BURBANK, Fred, H. [/];<br>O. LUBOCK, Paul [/]; O. JONES, Michael, L. [/]; O. QUICK,<br>Richard, L. [/]; O. CHOW, Y., Ping; O.   | <b>Published</b> |  |
| <b>(54) Title: ELECTROSURGICAL BIOPSY DEVICE AND METHOD</b><br><b>(54) Titre: DISPOSITIF ET PROCEDE DE BIOPSIE ELECTROCHIRURGICALE</b>   |                  |  |
| <b>(57) Abstract</b><br><p>An electrosurgical biopsy device includes a stylet and a cannula movably mounted on a base. The stylet has a shaft with a head at its distal end and a stylet ablation element extending distally from the head. The stylet shaft is disposed through the cannula for axial translation therein between withdrawn and extended positions. The cannula has an opening at its distal end and a cannula ablation element adjacent the opening. Both ablation elements are activatable with energy that ablates adjacent tissue. A translation mechanism controllably moves (a) the stylet between the withdrawn and extended positions and (b) the cannula between a proximal position and a distal position relative to the base. In use, with the stylet in the withdrawn position against the distal end of the cannula, and with the stylet ablation element activated, the stylet and the cannula are pushed through the skin and the underlying tissue until the stylet head is adjacent a targeted tissue mass. Next, the stylet is extended distally from the distal end of the cannula so that its head penetrates the tissue mass. The cannula ablation element is then activated, and the cannula is pushed through the tissue mass toward the stylet head, thereby cutting a "core" through the tissue mass that is captured as a tissue specimen within the distal end of the cannula. The cannula and the stylet are then removed from the patient's body.</p>   |                  |  |
| <b>(57) Abrégé</b><br><p>Ce dispositif de biopsie comprend un stylet ainsi qu'une canule montée mobile sur une base. Le stylet présente un axe doté d'une tête au niveau de son extrémité distale, ainsi qu'un élément d'ablation s'étendant de manière distale à partir de la tête. L'axe du stylet est disposé à travers la canule de manière à pouvoir effectuer une translation axiale dans la canule, entre une position escamotée et une position déployée. La canule présente une ouverture au niveau de son extrémité distale, ainsi qu'un élément d'ablation adjacent à cet ouverture. Les deux éléments d'ablation peuvent être activés avec l'énergie permettant l'ablation du tissu adjacent. Un mécanisme de translation déplace de manière régulée (a) le stylet, entre une position escamotée et une position déployée, et (b) la canule, entre une position proximale et une position distale par rapport à la base. Le procédé d'utilisation comprend les étapes consistant, lorsque le stylet est dans sa position escamotée et repose contre l'extrémité distale de la canule et que l'élément d'ablation du stylet est sous tension, à pousser le stylet et la canule à travers la peau et le tissu sous-jacent jusqu'à ce que la tête du stylet soit adjacente à une masse tissulaire cible, puis à déployer le stylet de manière distale, à partir de l'extrémité distale de la canule, de façon que sa tête pénètre dans la masse tissulaire, et alors à actionner l'élément d'ablation de la canule et à pousser la canule à travers la masse tissulaire, vers la tête du stylet, de manière à découper ainsi un _ noyau _ à travers la masse tissulaire, lequel est emprisonné en tant qu'échantillon tissulaire, dans l'extrémité distale de la canule, et enfin à enlever la canule et le stylet du corps du patient.</p> |                  |  |

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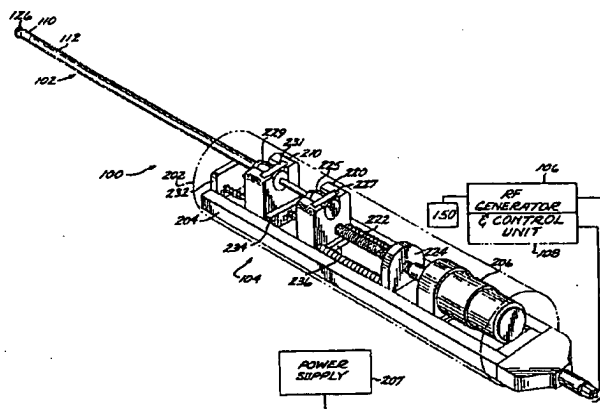
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|   |  |           | (43) International Publication Date: 30 March 2000 (30.03.00)  |
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| (22) International Filing Date: 17 September 1999 (17.09.99)  |  |           |  |
| (30) Priority Data:<br>09/159,467 23 September 1998 (23.09.98) US   |  |           |  |
| (71) Applicant: SENORX, INC. [US/US]; Suite 144, 13677 Alton Parkway, Irvine, CA 92618 (US).  |  |           |  |
| (72) Inventors: BURBANK, Fred, H.; 30982 Steeplechase Drive, San Juan Capistrano, CA 92675 (US). LUBOCK, Paul; 30 Bethany, Laguna Niguel, CA 92677 (US). JONES, Michael, L.; 34441 Camino El Molino, Capistrano Beach, CA 92624 (US). QUICK, Richard, L.; 32181 Fall River Road, Trabuco Canyon, CA 92679 (US). |  |           |  |
| (74) Agents: KLEIN, Howard, J. et al.; Klein & Szekeres, LLP, Suite 700, 4199 Campus Drive, Irvine, CA 92612 (US).  |  |           | (88) Date of publication of the international search report: 10 August 2000 (10.08.00)   |

Published

With international search report.

(54) Title: ELECTROSURGICAL BIOPSY DEVICE AND METHOD



(57) Abstract

An electrosurgical biopsy device includes a stylet and a cannula movably mounted on a base. The stylet has a shaft with a head at its distal end and a stylet ablation element extending distally from the head. The stylet shaft is disposed through the cannula for axial translation therein between withdrawn and extended positions. The cannula has an opening at its distal end and a cannula ablation element adjacent the opening. Both ablation elements are activatable with energy that ablates adjacent tissue. A translation mechanism controllably moves (a) the stylet between the withdrawn and extended positions and (b) the cannula between a proximal position and a distal position relative to the base. In use, with the stylet in the withdrawn position against the distal end of the cannula, and with the stylet ablation element activated, the stylet and the cannula are pushed through the skin and the underlying tissue until the stylet head is adjacent a targeted tissue mass. Next, the stylet is extended distally from the distal end of the cannula so that its head penetrates the tissue mass. The cannula ablation element is then activated, and the cannula is pushed through the tissue mass toward the stylet head, thereby cutting a "core" through the tissue mass that is captured as a tissue specimen within the distal end of the cannula. The cannula and the stylet are then removed from the patient's body.

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# INTERNATIONAL SEARCH REPORT

International Application No  
PC/JS 99/21416

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|------------|--|-----------------------|
| X          | US 5 470 308 A (LUNDQUIST INGEMAR H ET AL) 28 November 1995 (1995-11-28)<br>the whole document<br>column 10, line 63 -column 11, line 42 | 1-6,10,<br>11         |
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Date of the actual completion of the international search

22 December 1999

Date of mailing of the international search report

19. 05. 2000

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/21416

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 23-27  
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Rule 39.1(iv) PCT - Method for treatment of the human or animal body  
by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such  
an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

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1-13

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

**1. Claims: 1-13**

Biopsy device having a shaft and distal extending electrodes

**2. Claims: 14-22**

A biopsy device having coaxial stylet, a base for axial translation and first and second ablation elements.

# INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No.

PCT/US 99/21416

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